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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Woodard, Emhardt, Naughton, Moriarty and McNett
Bank One Center/Tower
Suite 3700
111 Monument Circle
Indianapolis, IN 46204-5137

EXAMINER	
LEAVITT, MARIA GOMEZ	
ART UNIT	PAPER NUMBER
1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/025,282	BLEYER ET AL.	
	Examiner	Art Unit	
	MARIA LEAVITT	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-60,62,66 and 67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-60,62,66 and 67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05-14-2009 has been entered.
2. Status of claims. Claims 54-60, 62, 66 and 67 are pending. Claims 54 and 67 have been amended by Applicants' amendment filed on 05-14-2009.
3. Therefore, claims 54-60, 62, 66 and 67 are currently under examination to which the following grounds of rejection are applicable.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to arguments

Applicants' request for an interview

Applicants' request for an interview at page 2 of the Remarks filed on 05-14-2009 is not in compliance with 37 CFR § 1.4(c): "each distinct subject, inquiry or order must be contained in a separate paper to avoid confusion and delay in answering papers dealing with different subjects"; as Applicants' correspondence contains both a response and a request for an interview. Should Applicants still desire an interview, one may be requested as set forth in 37 CFR § 1.133 by contacting the examiner of record by telephone and scheduling an interview in advance.

Rejections maintained in response to Applicants' arguments or amendments

Claims 54-60, 62, 66 and 67 remain rejected under 35 USC § 103 as being unpatentable over Badylak et al., (US Patent No. 6,099,567, effective priority filing date, 10 December 1996) in view of Stinson et al., (US 2004/0111149 A1, Date of filing August 1, 1997).

Badylak et al., discloses tissue graft compositions comprising the tunica submucosa of the intestine of warm-blooded vertebrates used as a matrix for the regrowth of tissues (col. 1, lines 21-32). Furthermore, Badylak et al., discloses that the stomach submucosa composition can be folded or partially everted to provide multiple layers for gripping, for example, with spiked washers or staples (col. 5. lines 50-55) or "multiple strips/pieces of stomach submucosa can be overlapped and compressed, under conditions allowing dehydration of the tissue, to fuse the strips/pieces of the stomach submucosal tissue into a unitary multi-laminate construct (col. 6, lines 4-7). Note that collagenous strips forming a multi-laminate construct necessarily present a first collagenous strip having both an external surface and an internal surface, said internal surface opposing the internal surface of an adjacent collagenous strip (**Current claims 54-55 and 62).** Moreover, Badylak et al., teaches that the stomach submucosa compositions can be administered to the host in either solid or sheet form by surgical implantation alone or in combination with other art-recognized implant compositions (col. 3, lines 65-67). In addition, Badylak et al., teaches that the submucosa composition is typically prepared from stomach tissue harvested from animals raised for meat production, including pigs (col. 2, lines 60-64) **Current claims 56, 59 and 60**. Insofar as the formulation of the implantable biomaterial in a lyophilized form (e.g., a freeze-dry procedure), Badylak et al., at column 3, lines 20-37, describes that the submucosa tissue is grinded in a frozen or freeze-dried state. Moreover, Badylak contemplates

the use of powder forms of stomach submucosa prepared by pulverizing stomach submucosal tissue under liquid nitrogen to produce particles which are then lyophilized overnight (col. 3, liens 39-45)**(Current claim 66).**

Badylak et al., does not specifically teach a radiopaque disposed between a first and a second collagenous strips of the layered structure.

However, at the time the invention was made, Stinson teaches that there is a need for bioabsorbable radiopaque markers for use on an implantable biomaterial such as an endoprosthesis, e.g., stents and grafts, in order to improve radiopacity and visualize the passage and placement of the endoprosthesis, particularly by using radiopaque endoprosthesis (p. 1, paragraphs [0002]-[0004]). Moreover, Stinson et al., discloses that bioabsorbable-radiopaque markers (e.g., 14) may have one or more hollow, cavity, or porous portions wherein radiopaque material may be disposed (p. 2, paragraph [0021]). Moreover, discrete bioabsorbable-radiopaque markers have the same functional purpose as the threaded markers, but they can be more easily used to mark the specific locations of features of interest on the stent (page 7, [0070]). In preferred embodiments Stinson teaches that the radiopaque agent is released from the implant into the systemic circulation to prevent encapsulation of the marker particles (page 2, paragraph [0020]). Furthermore, preferred metallic elements for biocompatibility and radiopacity as taught by Stinson include tantalum, bismuth and barium (p. 3, paragraph [0027]). Additionally, Stinson teaches that is preferable to use small amounts of the radiopaque substances in the implant by incorporating the discrete bioabsorbable-radiopaque marker rather than to load the entire implant with the radiopaque material in body tissue (p.2, paragraph 20). Note that the radiopaque collagenous biomaterial device of claim 67 is claimed as a product-by-process. "[E]ven though

product-by-process claims are limited by and defined by the process; determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) **(Current claims 57, 58 and 67).**

Therefore, in view of the benefits of using radiopaque markers in bioabsorbable graft material to enhance radiopacity and visualize the placement of the implantable graft, as taught by Stinson, it would have been *prima facie* obvious for one of ordinary skill in the art to incorporate a radiopaque marker in the implantable multilayer device taught by Badylak. A person of ordinary skill would have had a good reason to dispose the radiopaque marker between any of the strips of the multilayer implantable device (e.g., a first collagenous strip and a second collagenous strip) in an attempt to improve radiopacity for imaging, as a person with ordinary skill has good reason to pursue the known options within his grasp. The use of bioabsorbable collagenous materials as well as radiopaque elements was routine or well-established in the art at the time of filing. Furthermore, the disclosure of the specification as-filed fails to provide any new elements in the product as claimed.

Response to Applicants' Arguments as they apply to rejection of claims 54-60, 62, 66 and 67 under 35 USC § 103

At page 2 of the Remarks filed on 05-14-2009, Applicants essentially argue that the claims have been amended to recite that the radiopaque substance is positioned between opposing surfaces of a first collagenous strip and a second collagenous strip, thus providing a

localization for the radiopaque substance that would prevent or inhibit the substance from being released from the construct, in contrast to the bioabsorbable-radiopaque marker of Stinson. Additionally, Applicants allege that the position of a radiopaque between opposing layers could provide a local increased concentration of the radiopaque between layers. The above arguments have been fully considered but deemed unpersuasive.

The instant invention is drawn to a bioabsorbable collagenous, radiopaque biomaterial device. The combined disclosure of Badylak and Stinson obviate the instant claims in relation to layered structures comprising a first collagenous strip and a second collagenous wherein a radiopaque marker is positioned between the strips. So if the radiopaque marker added to the bioabsorbable collagenous biomaterial is released from the implant as the bioabsorbable material degrades as disclosed by Stinson, positioning the radiopaque marker between opposing biodegradable collagenous strips should be reasonably expected to result in release into the systemic circulation for the same reason the radiopaque marker in the bioabsorbable material of Stinson is released into the body -a bioabsorbable material degrades when implanted in the body over time. Applicant has not provided probative evidence to the contrary. Furthermore, the disclosure of the specification as-filed fails to provide any new elements in the product as claimed.

New Grounds of Rejection

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 54-60, 62, 66 and 67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 54 is indefinite in the reciting at lines 9-11 of "said layered structure including a first collagenous strip having an exterior surface opposing an exterior surface of a second collagenous strip … a radiopaque marker positioned between said opposing exterior surfaces of said first collagenous strip and said second collagenous strip". Likewise, claim 67 is indefinite in the reciting at lines 9-12 of "in which an exterior surface of the first collagenous layer opposes an exterior surface of the second collagenous layer and in which the radiopaque marker is located between opposing exterior surfaces". Figure 4, wherein support for the new limitations is found, illustrates two layers of collagenous material (i.e., 20). Each layer comprises an exterior surface and an interior surface which opposes the interior surface of the other layer. The radiopaque marker (i.e., 16) is deposited or positioned between the opposing internal surfaces of each collagenous layer (e.g., a first and a second layer). Classically, an exterior surface of a first and a second layer become interior surfaces when opposed to each other. Thus, it is unclear how the radiopaque marker is positioned between opposing exterior surfaces as claimed. Thus, the metes and bounds are not clearly set forth.

Claims 55-60, 62, 66 are indefinite insofar as they depend from claim 54.

For the purpose of compact prosecution the radiopaque marker has been interpreted as positioned between the inner surfaces of the opposing layers.

Conclusion

Claims 54-60, 62, 66 and 67 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria Leavitt whose telephone number is 571-272-1085. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1633; Central Fax No. (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

/Maria Leavitt/

Maria Leavitt, PhD
Examiner, Art Unit 1633